

C L A I M S

1. An external urinary catheter device for the relief of male urinary incontinence, comprising

5 a contact member (1) adapted for arrangement, in a position of use, in engagement with at least an extreme portion (3) of a penis (4),

an opening (5) formed in a distal end section (6) of the contact member (1) to be positioned substantially opposite the urethral orifice in the position of use,

10 a discharge conduit (7) connected with the opening (5) to provide a sealed urine flow passage extending in a substantial axial direction towards the exterior of the catheter device,

15 an aperture (8) provided in a distal part of the contact member or in the discharge conduit (7),

a membrane (9) attached to the surface surrounding said aperture (8) and capable of selectively passing gases but retaining urine,

20 an external protective shield (10) arranged for at least partly covering the membrane, and

at least one vent (11, 14, 18, 29, 30) provided for allowing gases to be in substantially unhindered contact with the external surface of the membrane.

25 2. The external urinary catheter device according to claim 1, wherein the contact member (1) is integrally connected with discharge conduit (7) via the opening (5) formed in the distal end section of the contact member (1).

30 3. The external urinary catheter device according to claim 1 or 2, wherein the contact member (1) is arrangeable, in a position of use, between the foreskin (2) and the corona (3) of a penis (4),

4. The external urinary catheter device according to claim 3, wherein the contact member (1) comprises a shoulder-like ledge (13) at a substantially plane abutment face of the contact member (1) around
5 and substantially perpendicular to the discharge conduit (7).

5. The external urinary catheter device according to claim 3, wherein the contact member (1) comprises a plurality of leaves comprised of a film having an adhesive layer on the interior surface thereof
10 to secure an attachment of the device to the corona of a penis.

6. The external urinary catheter device according to any of the preceding claims, wherein the contact member (1) constitutes an inner member of the
15 catheter device, the catheter device further comprising an outer holder member (12) for retaining the contact member (1) in the position of use, said outer holder member (12) being formed in a distal end section thereof with an opening for said discharge conduit (7) and being arrangeable, in said position of
20 use, in a substantially fixed axial position with respect to the discharge conduit (7) for circumferential engagement with the external side of the foreskin (3).

25 7. The external urinary catheter device according to any of the preceding claims, wherein the membrane (9) is attached to said surrounding surface by means of an adhesive (23).

8. The external urinary catheter device according to any of claims 1 to 6, wherein the membrane (9)
30 is attached to said surrounding surface by means of a rivet member (24).

9. The external urinary catheter device according to any of claims 1 to 6, wherein the membrane (9) is attached to said surrounding surface by welding.

5 10. The external urinary catheter device according to any of claims 1 to 9, wherein the membrane (9) is adapted to allow passage of urine at pressures more than 80 mbar above ambient pressure.

10 11. The external urinary catheter device according to any of the preceding claims, wherein said aperture (8) is provided in the discharge conduit (7) of the contact member (1) and said shield (10) comprises a tubular member (20) surrounding the discharge conduit (7) to cover said aperture (8) and the membrane (9) attached to said surrounding surface.

15 12. The external urinary catheter device according to claims 6 and 11, wherein said tubular member (20) forms part of the outer holder member (12).

20 13. The external urinary catheter device according to claim 12, wherein the outer holder member (12) is fixed in at least an axial direction with respect to the inner member (1) by fastening means.

25 14. The external urinary catheter device according to claim 13, wherein the outer holder member (12) is fixed in an axial direction as well as a rotational direction with respect to the inner member (1) by fastening means.

30 15. The external urinary catheter device according to claim 13 or 14, wherein said tubular member (20) forms an integral part of said outer holder member (12) and is connected by said fastening means with a proximal part of the discharge conduit (7) of the inner member (1).

16. The external urinary catheter device according to claim 15, wherein said fastening means comprises one or more ledges (31) in the inner face of the tubular member (20) and/or the outer face of the discharge conduit (7).

17. The external urinary catheter device according to claim 15, wherein said fastening means comprises a membrane device (34) arranged in an aperture going through said tubular member (20) as well as said proximal part of the discharge conduit (7).

18. The external urinary catheter device according to any of claims 13 to 15, wherein said fastening means comprises a thermal or an ultrasonic welding bond.

19. The external urinary catheter device according to any of the preceding claims, wherein said vent comprises at least one opening (11, 14) in said shield (10) in flow communication with the external surface of the membrane (9).

20. The external urinary catheter device according to any of the preceding claims, wherein the membrane (9) is depressed with respect to said surrounding surface to provide a clearance with respect to said shield (10) and said vent comprises at least one track (18, 29, 30) formed by a depression in an internal surface of said shield (10) and/or said surrounding surface part to provide a gas flow communication between said clearance and the exterior of the catheter device.

21. A method for production of an external urinary catheter device for the relief of male urinary incontinence, which comprises the steps of:

providing a catheter part comprising a contact member (1) which is adapted for engagement with at least an extreme portion (3) of a penis (4), said contact member comprising a distal end section (6) providing an opening (5) located to be positioned substantially opposite the urethral orifice by said engagement of the contact member (1) with said extreme portion (3) and a discharge conduit (7) connected with the opening (5),

10 providing an aperture (8) in a distal part of the contact member (1) or in the discharge conduit (7),

attaching a membrane (9) to the surface surrounding said aperture (8), the membrane being capable of selectively passing gases but retaining urine,

15 providing a protective shield (10) for at least partly covering protect the membrane, and

arranging at least one vent (11, 14, 18, 29, 30) for allowing gases to be in substantially unhindered contact with the external surface of the membrane.

20 22. The method according to claim 21, wherein said aperture (8) is provided in the discharge conduit (7) of the contact member (1) and said shield (10) comprises a tubular member (20) and is provided to surround the discharge conduit (7) to cover said aperture (8) and the membrane (9) attached to said surrounding surface.

23. The method according to claim 21 or 22, further comprising the step of providing the catheter part with an outer holder member (12) for retaining the contact member (1) in a position of use as an inner member between the foreskin (2) and the corona (3) of a penis (4), said outer holder member (12) being

formed in a distal end section with an opening for said discharge conduit (7) and being adapted for arrangement, in a position of use, in a substantially fixed axial position with respect to the discharge conduit (7) for circumferential engagement with the external side of the foreskin (2).

24. The method according to claims 22 and 23, wherein said tubular member (20) is formed as part of the outer holder member (12).

25. The method according to claim 24, wherein the outer holder member (12) is provided to be fixed in at least an axial direction with respect to the inner member (1) by fastening means.

26. The method according to claim 25, wherein said tubular member (20) is formed as an integral part of said outer holder member (12) and said fastening means is provided to connect said tubular member (20) with a proximal part of the discharge conduit (7) of the inner member (1).

27. The method according to claim 25 or 26, wherein said fastening means is provided by a thermal or an ultrasonic welding.

28. The method according to any of claims 21 to 27, wherein said catheter part is provided by a process comprising the steps of

- a) providing a liquid polymer solution or emulsion comprising a polymer and a solvent or a diluent in an amount sufficient for permitting dip forming,
- b) providing a form having a first part for forming said contact member, a second part for forming said opening in the distal end section of the contact member and a third part for forming said

discharge conduit, said first, second and third parts being integrally connected,

- c) dipping said form in said solution or emulsion,
- d) removing the form from the solution or emulsion,
- 5 e) allowing the solvent or the diluent to evaporate, and
- f) optionally, repeating the steps c), d), and e) until the device has attained a desired wall-thickness, and

10 wherein, prior to dipping according to step c) or during evaporation according to step e), said membrane is arranged at the part of the form for forming the distal part of the contact member or at the third part of the form for forming the discharge conduit.

15 29. The method according to any of claims 21 to 27, wherein said catheter part is provided by a process comprising the steps of

providing a mould comprising a matrix and a core member defining a mould cavity for plastic injection
20 moulding, said cavity comprising a first part for forming said contact member, a second part for forming said opening in the distal end section of the contact member and a third part for forming said discharge conduit, said first, second and third parts being in-
25 tegrally connected,

injection of a liquid plastic material into said mould cavity,

solidification of the liquid plastic material,
and

30 recovering the moulded device from the mould,
and

wherein said membrane is arranged at the part of the cavity for forming the distal part of the contact mem-

ber or the third part of the cavity for forming the discharge conduit.

30. A process for manufacture of an external urinary catheter for the relief of male urinary incontinence comprising the steps of

- a) providing a liquid polymer solution or emulsion comprising a polymer and a solvent or a diluent in an amount sufficient for permitting dip forming,
- 10 b) providing a form having a first part for forming said contact member, a second part for forming said opening in the distal end section of the contact member and a third part for forming said discharge conduit, said first, second and third
- 15 parts being integrally connected,
- c) dipping said form in said solution or emulsion,
- d) removing the form from the solution or emulsion,
- e) allowing the solvent or the diluent to evaporate, and
- 20 f) optionally, repeating the steps c), d), and e) until the device has attained a desired wall-thickness, and

wherein, prior to dipping according to step c) or during evaporation according to step e), said membrane is arranged at the part of the form for forming the distal part of the contact member or at the third part of the form for forming the discharge conduit.

31. An external urinary catheter device obtainable by the process according to claim 30.

30 32. A process for manufacture of an external urinary catheter for the relief of male urinary incontinence comprising the steps of

providing a mould comprising a matrix and a core member defining a mould cavity for plastic injection moulding, said cavity comprising a first part for forming said contact member, a second part for forming said opening in the distal end section of the contact member and a third part for forming said discharge conduit, said first, second and third parts being integrally connected,

injection of a liquid plastic material into said mould cavity,
solidification of the liquid plastic material,
and

recovering the moulded device from the mould,
and

wherein said membrane is arranged at the part of the cavity for forming the distal part of the contact member or the third part of the cavity for forming the discharge conduit.

33. An external urinary catheter device obtainable by the process according to claim 32.

34. A kit for relief of male urinary incontinence comprising

an external urinary catheter device according to any of claims 1 to 20, 31 or 33.

a bag for collection of urine discharged from the catheter device, and

a hose member for connecting the catheter device and the bag.

35. Use of the external urinary catheter device according to any of claims 1 to 20, 31 or 33 or the kit according to claim 34 for relief of male urinary incontinence.